Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2014

Agriculture

Question: 48

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Information supplied by Fruitwest

Proof Hansard page: 66

Senator LINES asked:

Ms Arthy: That was raised in a private briefing that we had last year. At the time, I just gave an undertaking to contact Fruitwest to see if they had the information, because as the APVMA we have got no powers to request that information. I think I sent the request just after Christmas. I have been away for a couple of weeks; this is my first day back. From what I understand, Fruitwest got in contact with some of our officers and said that they had supplied the information directly to the committee. I think all I can do is to go back to Fruitwest with my original request and just check, because I have not seen the Fruitwest submission into the inquiry, but I can follow it up.

Answer:

On 18 March 2014 the Australian Pesticides and Veterinary Medicines Authority (APVMA) wrote to Fruitwest advising that the Committee has requested the APVMA to approach Fruitwest to request information regarding the ratio of growers who are concerned about the withdrawal of fenthion as opposed to those growers who are able to manage without it. In this request, the APVMA advised that Fruitwest should provide any additional information direct to the Committee.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2014

Agriculture

Question: 49

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: APVMA's call for public comment

Proof Hansard page: 67

Senator RUSTON asked:

Senator RUSTON: that transpired from 1998 to 2012 where it became more obvious that something was not right? That is an awfully long period of time.

Dr Bhula: Because fenthion is used across horticultural products as well as veterinary products and bird repellent products, we broke the review into two parts. We looked at the non-food producing components of the fenthion first and then we looked at the horticultural products. In that first round of looking at the non-food uses we also looked at a human health and toxicology assessment. That was published in 2005, so that would have been the first trigger for people looking at the horticultural products that the health standards had changed. We completed our review of the bird repellent products, which I would have to take on notice but I think it was about 2009-2010.

Answer:

The Preliminary Review Findings for non-food producing uses of fenthion was published in December 2005. The recommendations were that registration could continue only if risks to non-target birds could be managed through declaration as Restricted Chemical Products. The process for this declaration was completed in December 2009.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2014

Agriculture

Question: 50

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicine Authority

Topic: Chemicals becoming generic

Proof Hansard page: 70

Senator BACK asked:

Senator BACK: Does it change the dialogue in any way once that chemical becomes a generic and is out of patent? Does that make the process easier for all concerned or does it have no effect on it?

Ms Arthy: I would have to think that one through, because the issue does come down to commercial-in-confidence information.

Senator BACK: It does.

Ms Arthy: We can talk it through and come back to you separately, if you would like more information.

Senator BACK: I am happy for you to take it on notice and advise the committee in due course.

Ms Arthy: We will take it on notice.

Answer:

When a product becomes a generic, patents and data protection have lapsed making it easier to use and access information associated with that chemical.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2014

Agriculture

Question: 51

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Fenthion

Proof Hansard page: Written

Senator STERLE asked:

1. Do you acknowledge that there are deficiencies in the communication processes within the APVMA when dealing with stakeholders? I believe the only answer must be yes.
2. Work regarding the safe use of fenthion has been ongoing since 1998, can you inform the committee if fenthion will be permanently banned/restricted and detail if this will be across the board on all horticultural products?
3. One of the key responsibilities of the APVMA is providing timely services and managing issues related to assessing applications to register or permit use of pesticides, what procedures and processes has the APVMA undertaken to achieve this with regards to fenthion?
4. Has the APVMA met its responsibility with regards to providing a timely service and managing the issues related with fenthion?
5. Is the APVMA considering phase out for fenthion rather than a straight out ban?
6. Will you confirm that the data regarding fenthion toxicity is that it breaks down into six products and can you provide detail as to which of the 6 breakdown products are most toxic?
7. Are there other products currently used in Fruit fly pest management that have any of these breakdown products?
8. Since the APVMA is limited in its role by its legal powers, can the Department detail the communication process with stakeholders when a chemical is restricted, but an effective alternative product is not available?
9. Can you confirm that it is not part of the APVMA's role and responsibility to conduct research or to generate any data?
10. Has the Minister sought advice on the fenthion issues

Question: 51 (continued)

Answer:

1. As outlined in the evidence given by the Australian Pesticides and Veterinary Medicines Authority (APVMA) Chief Executive Officer to Senator Lines' question of the 25th February 2014 (p66 Hansard), the APVMA recognises that stakeholder communication presents challenges for any government agency. The APVMA undertakes extensive communication with state and territory governments, relevant commonwealth government agencies, registrants and affected industry bodies as part of the chemical review process. This includes through email updates when further information or reports become available, attendance at user group meetings, targeted information sessions provided at various regional centres and publication in rural based magazines and journals. The APVMA cannot communicate directly with every individual grower and is therefore reliant on the networks of State and Territory and industry bodies to communicate directly with growers. The APVMA acknowledges that there is always room for improving stakeholder communication, but there will always be a case where individual growers may not necessarily understand proposed regulatory decisions.

2. The fenthion review is yet to be completed. A standard three month public consultation process applies to proposed to chemical review outcomes. Following the receipt and evaluation of any submissions received during this public consultation process, the APVMA will consider the next steps to finalise the review.

3. The evaluation of any application by the APVMA is subject to a legislative timeframe. This is clearly set out in information to applicants available in the APVMA Manual of Requirements and Guidelines (MORAG).

4. The APVMA has met its legislative obligations to evaluate the potential risks to human health from the use of fenthion, while concomitantly affording industry multiple opportunities to generate additional Australian data from approximately 2004 to present.

5. The APVMA is yet to make a decision on the review of fenthion. Part of that decision will be whether a phase-out or complete ban is appropriate. This will be published as part of the Preliminary Review Findings for fenthion. Once the period for public comments or submission of relevant information has ended, the APVMA will consider options based on information submitted in response to the final proposed decision.

6. The breakdown products of fenthion are included in the Australian residue definition for fenthion which is the "*Sum of fenthion, its oxygen analogue, and their sulfoxides and sulfones, expressed as fenthion*". These can also be described as:

    a. Fenthion, fenthion sulfone, fenthion sulfoxide,
    fenthion oxon, fenthion oxon sulfone, and fenthion oxon sulfoxide.

    b. Of these metabolites the most toxic when given by mouth is fenthion oxon sulfone. Fenthion oxon and fenthion oxon sulfoxide are also more toxic than fenthion.

7. No.

Question: 51 (continued)

8. There are numerous avenues of communication open to the Department, beyond that used by the APVMA, to discuss the impacts of restrictions to chemicals. These include talking to research and development corporations and forming ad-hoc committees, as was done for fenthion with the formation of the Dimethoate Fenthion Response Coordination Committee (DFRCC). However, there is no specific process, as reviews do not always result in the loss of a chemical without effective alternatives being available.

9. Yes.

10. Yes.

Rural and Regional Affairs and Transport Legislation Committee

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Agriculture

Question: 52

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: APVMA's call for public comment

Proof Hansard page: Written

Senator STERLE asked:

Can you provide information to the committee regarding the APVMA's call for public comment for some proposed variations to the Food Standards Code, Schedule 1 to Standard 1.4.2 – Maximum Residue Limits

Answer:

The Food Standards Australia New Zealand Amendment Act 2010 came into effect on 1 March 2011. That Act introduced changes to the legislation of both the Australian Pesticides and Veterinary Medicines Authority (APVMA) and FSANZ to allow the APVMA to directly vary Standard 1.4.2 of the Australia New Zealand Food Standards Code following a period of public consultation.

These changes came about following the 2008 Productivity Commission report into the Regulation of Chemicals and Plastics, which recommended direct adoption of APVMA MRLs into the Food Standards Code, to remove the time lags that existed between promulgation of MRLs from the APVMA MRL Standard to the Food Standards Code. COAG endorsed that recommendation.